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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/621,146	07/21/2000	Chryslain Sumian	BJA 254A	3940
7590 02/10/2006 Bolesh J Skutnik PhD JD 515 Shaker Road East Longmeadow, MA 01028			EXAMINER KISHORE, GOLLAMUDI S	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 02/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/621,146

Applicant(s)

SUMIAN, CHRYSLAIN

Examiner

Gollamudi S. Kishore, Ph.D

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5,9-16 and 18-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2, 5, 9-16 and 18-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The RCE dated 11-4-05 is acknowledged.

Claims included in the prosecution are 1-2, 5, 9-16 and 18-24.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-2, 5, 9-16 and 18-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant amends claim 1 to recite an additional step d. which recites, "applying said compound/drug to said hair follicle area through said follicle lumen for increased application of the compound/drug to said animals and humans". According to step a, the compound/drug and the swellable composition are simultaneously applied. The amended claims require the application of the compound/drug twice that is simultaneously along with the swellable composition and again after applying the swellable composition. There is no support for this concept in the specification as originally filed and therefore, deemed to be new matter.

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3. Claims 1-2, 5, 9-116 and 18-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There are three figures in the specification and in the brief description of figures 2 and 3 apparently deal with the hair follicle reaction after a swellable composition is applied. However, nowhere in the specification one can find what swellable composition is applied. In fact, with regard to swellable composition, the specification only refers to some prior art and does not specifically disclose what compositions come under swellable compositions and what the gels, lotions, creams and others recited on page 9 of the specification contains. In fact, on page 9 of the specification states, "In one preferred embodiment, the substance is a form of microsphere or liposome. As disclosed in EP 03750520 and WO 98/48716, formulations containing specific size of ingredients (e.g. microspheres or liposomes) may target compounds to follicles". First of all, according to instant claim 18, the polymers are encapsulated in liposomes whereas according to applicant's statement above refers to the 'substance *is* a form of liposomes'. This means the liposome itself is a swellable composition. These two concepts are totally different. There is no guidance provided in the specification for either of the concepts for one of ordinary skill in the art to practice the invention without undue experimentation. Secondly there is no EP patent with the number recited. Thirdly, according to the English equivalent of the WO reference cited (US 6,287,549) the microspheres are made from even fatty substances

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(WO is one of the references which applicant recites as a guidance for the selection of swellable composition) such as fatty alcohols and triglycerides for the preparation of microspheres (col. 2, line 63 through col. 3, line 2). These are lipophilic compounds (water repellants) and it is unclear as to how they can swell within the follicles.

According to col. 3, lines 3-5 of US 6,287,549, "vesicular microparticles may also be used as liposomes and, preferably, polymerized liposomes whether reverse or forward".

This statement clearly implies that liposomes themselves are microparticles and not that the polymers are within the liposomes. In essence, instant specification does not provide adequate guidance to one of ordinary skill in the art as to which swellable compounds come under the definition of swellable compositions or how to use liposomes in practicing the invention without undue experimentation.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that swellable composition is noted on pages 5-13. This argument is not persuasive since at these locations, swellable polymers are disclosed, but not swellable **compositions**. For example, according to the specification, the compositions can be in the form of lotions, gels and creams meaning that there is some water in the composition. That means the swellable polymers are in an already swollen state before application. The specification does not disclose as to what is present in the gels, creams and lotions so as to enable one to apply the composition and then allow it to swell within the follicle. Applicant argues that the examiner 'must be confused' between lipophilic and hydrophobic. The examiner disagrees and points out that the applicant has misunderstood the issue. The examiner was questioning as to how a lipid

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material, which has no hydrophilicity at all, can swell within the follicle since swelling is a property exhibited by a compound upon absorption of water. Lipophilic compounds do not absorb water and swell. Since liposomes are made of phospholipids (not hydrophilic), they do not swell and applicant has not shown that to be otherwise. Instant specification does not provide adequate guidance for one of ordinary skill in the art to practice the invention without undue experimentation. The rejection is maintained.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-2, 5, 9-16 and 18-24 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear as to what applicant intends to convey by 'applying said compound/drug to said follicle area through said follicle lumen' in claim 1. Is the compound applied into the lumen or applied topically on the skin so that the compound penetrates the lumen? What is meant by 'for **increased application** of the compound? Does applicant mean increased amounts in the lumen? Step a already recites the simultaneous application of the compound and the swellable composition. Does that mean an additional amount of the compound is applied?

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It is unclear as to what applicant intends to convey by 'compound/drug are molecules and their derivatives used in cosmetic/pharmaceutical applications'. A derivative of a compound will still be a compound and a derivative of a drug will still be a drug if it has the same properties of the drug; if not there is no point in administering a derivative, which is not a drug.

It is unclear as to what applicant intends to convey by 'photosensitizer molecules, their derivatives and their precursors used in photodynamic therapy' as recited in claim 11. If the derivatives and precursors have photosensitizing property, then they also come under the category of 'photosensitizer molecules'. The examiner suggests the deletion of ', their derivatives and their precursors'.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that the examiner has taken the words out of context because the meaning present is clear and applicant tries to explain. These arguments are not persuasive since applicant misunderstood the issue raised by the examiner; that is if a derivative of a photosensitizer molecule has the same properties then it can also be called as a photosensitizer. If it does not have those properties, what is the point in administering a derivative, which is not photosensitizer, and which is not even a drug?

This rejection is maintained since contrary to the indication, the term, 'derivatives' is still in the claim.

Claim 12 specifies that the swellable composition of claim 1 to be cosmetically/pharmaceutically acceptable. Does this mean that the composition of claim 1 includes even cosmetically/pharmaceutically non-acceptable compositions?

Applicant points out page 8, lines 21-25 and page 9, line 25 regarding this issue. These locations however, define what cosmetically/pharmaceutically acceptable composition is; the response however, does not address the issue raised by the examiner as to whether that the composition of claim 1 includes even cosmetically/pharmaceutically non-acceptable compositions.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-2, 5, 9-16, 18 and 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/48716 of record (English equivalent: US 6,287,549).

WO teaches a method wherein a swellable polymeric particle or polymeric liposomal composition containing chromophores (phthalocyanins) is applied onto the skin. Since the composition in WO is the same as in instant application, instant steps, instant steps b and c are inherent in prior art; a composition containing chromophores in a solvent is applied to the surface of the skin

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(instant step d). Since the same polymers are used they would swell the same way in instant method and the method in the prior art. The reference further teaches shaving the surface of the skin to be treated in order to make the hair follicles more accessible (see abstract, col. 2, line 17 through col. 3, line 50, col. 4, lines 8-12, col. 5, lines 62-67 and claims). WO does not provide specific examples showing the method using the liposomes (there are no examples in instant specification either). However, in view of the guidance provided by WO, it is deemed obvious to one of ordinary skill in the art to use liposomes with a reasonable expectation of success.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that Sumian et al disclose the use of microparticles to destroy the hair follicle by laser light to create a shock wave and that the claims of Sumian et al being 4 steps involve the removing the composition from the skin and the application of laser energy. This is not required in claim 1 of the present invention. This argument is not persuasive since in Simian et al, the composition which is on the surface of the skin is removed and not the composition within the hair follicle. Furthermore, instant claim language does not exclude the removal of the composition present on the skin surface and further manipulations such as application of laser energy.

8. Claims 1-2, 5, 9-16, 18 and 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schaefer (5,292,512) by itself or in combination with WO 98/48716 of record (English equivalent: US 6,287,549).

Schaefer teaches a method wherein a swellable polymeric particle composition containing various active agents is applied onto the skin for selective entry into follicles. The composition is applied to the skin with a gentle massage. Since the composition in Schaefer is the same as in instant application, instant steps, instant steps b and c are inherent in prior art; since the same polymers are used they would swell the same way in instant method and the method in the prior art (see abstract, col. 2, line 5 through col. 4, line 54, col. 5, line 1 through col. 8, line 35, Examples and claims). What is lacking in Schaefer is the teaching of the removal of hair before application of the swellable composition. However, since the purpose of the method is to make the active agent in the composition to penetrate the follicles, it is within the skill of the art to realize that the maximum penetration occurs when the hairs are shaved or cut before the application of the composition. Furthermore, one of ordinary skill in the art would be motivated to shave the skin in view of WO teachings that shaving makes the hair follicles more accessible. Schaefer also does not teach the application of additional compound. However, in the absence of showing unexpected results, it is deemed to be within the skill of the art to apply additional active agent to the skin if an increased amount is needed to achieve the purpose. One of ordinary skill in the art would be motivated to apply additional compound with a reasonable expectation of success since WO 98 which is concerned with the penetration of an active agent in the hair follicles teaches that compound in a solvent could be applied.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that in Schaefer the solvent is noted as the swelling agent

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for the microspheres themselves and that the composition is applied to the skin and enters the pilosebaceous orifices. This argument is not persuasive since Schaefer teaches on col. 7, lines 5-6 that the microspheres of 1-3 micrometers enter the follicles and there is nothing in Schaefer to indicate that the applied composition does not swell in the follicles. Schaefer teaches the composition in the form of gels just as in instant application (see specification on page 9, line 2 which recites gel). It should be noted that instant specification does not provide any information about the constituents of the gels. Instant specification does not specifically state what is present in the composition besides the swellable polymers. Applicant further argues that as contrasted with the present invention, Schaefer does not remove the hair and does not apply the swellable composition for the purpose of holding the opening the hair lumens for the infusion of chemicals therein. This argument is not found to be persuasive since as pointed out above, it is within the skill of the art to realize that the maximum penetration occurs when the hairs are shaved or cut before the application of the composition and WO is also suggestive of shaving the skin before application of the composition; since Schaefer applies the same composition, the opening of the hair lumens by the composition would be an inherent function of the composition itself.

9. Claims 1-2, 5, 9-16 and 18-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/48716 of record (English equivalent: US 6,287,549) cited above, further in view of Li (5,914,126) and/or Nakamura, 1980.

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The teachings of WO have been discussed above. What is also lacking in WO is the teaching of the occlusion of the area wherein the composition was applied with a cover.

Li while disclosing liposomal compositions for the delivery of the active agents to hair follicles teaches preshaving of the area to be treated and subsequent band-aid patch to immobilize the composition onto the skin to prevent evaporation (abstract, col. 41, line 62 through col. 42, line 2 and claims).

Nakamura while disclosing the anti-inflammatory activity of a topical glucocorticoid, fludroxycortide teaches that the depilation of the backs of the rats and then applying the tape containing fludroxycortide (abstract).

Preshaving of the skin or removing the hair and the occlusion of the area where the composition was applied would have been obvious to one of ordinary skill in the art since these are routinely practiced in the art as evident from Li and also from Nakamura. One of ordinary skill in the art would be motivated further to use liposomes, since liposomes are sustained release compositions and have been used in the art for the delivery of active agents as evident from Li.

Applicant's arguments have been fully considered, but are not persuasive. Applicant argues that from the text of Li, it is clear that the removal of hair was for the purpose of harvesting the skin for examination and also the band-aid was for the purpose of preventing removal and evaporation and neither of these features were the concern in the present invention. These arguments are not persuasive since WO teaches the accessibility of the hair follicles by shaving and the motivation to cover the

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skin need not be the same as applicants. Furthermore, Li uses the covering to immobilize the composition.

10. Claims 1-2, 5, 9-16 and 18-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schaefer cited above, further in view of Li (5,914,126) and/or Nakamura (1980).

The teachings of Schaefer have been discussed above. As pointed out above, what is lacking in Schaefer is the teaching of the removal of hair before application of the swellable composition. What is also lacking in Schaefer is the teaching of the occlusion of the area wherein the composition was applied with a cover.

Li while disclosing liposomal compositions for the delivery of the active agents to hair follicles teaches preshaving of the area to be treated and subsequent band-aid patch to immobilize the composition onto the skin to prevent evaporation (abstract, col. 41, line 62 through col. 42, line 2 and claims).

Nakamura while disclosing the anti-inflammatory activity of a topical glucocorticoid, fludroxycortide teaches that the depilation of the backs of the rats and then applying the tape containing fludroxycortide (abstract).

Preshaving of the skin and the occlusion of the area where the composition was applied would have been obvious to one of ordinary skill in the art since these are routinely practiced in the art as evident from Li and Nakamura.

Applicant's arguments with regard to Schaefer, Li and Nakamura have been addressed above. Applicant provides no other specific arguments regarding this rejection. The rejection is maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Gollamudi S Kishore, Ph.D
Primary Examiner
Art Unit 1615